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EXHIBIT B

# Integrity Agreement Between the Oppice of Inspector General Of the Department of Health and Human Services And Angelo Luzzi, D.P.M.

# L PREAMBLE

Angelo Luzzi, D.P.M. ("Luzzi") hereby agrees to enter into this Integrity
Agreement ("Agreement") with the Office of Inspector General of the United States
Department of Health and Human Services ("OIG") to provide for the establishment of
certain integrity measures to ensure compliance with the requirements of Medicare,
Medicaid and other Federal health care programs (as defined in 42 U.S.C. § 1320a-7b(f))
by Luzzi, Luzzi's employees and agents, any entity in which Luzzi is an owner or has a
control interest (as defined in 42 U.S.C. § 1320a-3(a)(3)), and all third parties with whom
Luzzi may choose to engage to act as billing or coding consultants for purposes of
claiming reimbursement from the Federal health care programs. Luzzi's compliance with
the terms and conditions of this Agreement shall constitute an element of Luzzi's present
responsibility with regard to participation in the Federal health care programs.
Contemporaneously with this Agreement, Luzzi is entering into a Settlement Agreement
with the United States. This Agreement is incorporated by reference into the Settlement
Agreement.

## II. TERM OF THE AGREEMENT

Except as otherwise provided in this Agreement, the period of compliance obligations assumed by Luzzi under this Agreement shall be five (5) years from the date of execution of this Agreement. The effective date of this Agreement shall be the date on which the final signatory executes this Agreement (the "effective date").

# III. INTEGRITY OBLIGATIONS

Within thirty (30) days of the date of the effective date of this Agreement, Luzzi agrees to implement an Integrity Program (the "Program"), which shall include the following provisions:

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## A. COMPLIANCE CONTACT

Within fifteen (15) days of the effective date of this Agreement, Luzzi shall designate a person to be the contact person for purposes of the obligations herein. At all times during the term of this Agreement, there shall be a contact person who shall have operational responsibility for ensuring compliance with the integrity obligations in this Agreement. If a new contact person is designated during the term of this Agreement, Luzzi shall notify the OIG, in writing, within ten (10) days of such a change.

## B. POSTING OF NOTICE

Within fifteen (15) days of the effective date of this Agreement, Luzzi shall post in a prominent place accessible to all patients and employees a notice detailing his commitment to comply with applicable statutes, regulations and written directives applicable to the Medicare, Medicaid and other Federal health care programs in the conduct of his medical practice and in seeking reimbursement for services and items furnished to patients of the Federal health care programs. This notice shall identify a means (i.e., telephone number, address, etc.) through which matters of concern can be reported anonymously.

# C. WRITTEN POLICIES AND PROCEDURES

Luzzi agrees to develop and implement written policies and procedures within sixty (60) days of the effective date of this Agreement, which written policies and procedures shall address the following:

- a. Luzzi's commitment to adhere to honest and accurate billing practices; and
- The proper submission of claims to the Federal health care programs, including verification that all claims meet applicable reimbursement standards;
- c. The proper documentation of services and billing information and the retention of such information in a readily retrievable form;
- d. A mechanism for employees and agents to make inquiries regarding compliance with medical practice standards and Federal health care program reimbursement standards without risk of retaliation or other

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e. Luzzi's commitment not to hire or engage as contractors any Ineligible Person. For purposes of this Agreement, an "Ineligible Person" shall be any individual or entity who: (i) is currently excluded, suspended, debarred or otherwise ineligible to participate in the Federal health care programs; or (ii) has been convicted of a criminal offense related to the provision of health care items or services and has not been reinstated in the Federal health care programs after a period of exclusion, suspension, deharment, or ineligibility.

## D. TRAINING AND CERTIFICATION

Within ninety (90) days of the effective date of this Agreement, Luzzi, Luzzi's employees and anyone else engaged by Luzzi to prepare or submit claims for reimbursement to the Federal health care programs shall be trained in the proper reimbursement standards, program policies, and verification and compliance procedures to ensure the propriety and accuracy of claims for scrvices and items furnished to Federal health care programs patients. The training shall be designed to ensure that Luzzi and all of his employees and agents are aware of all applicable Federal health care program statutes, regulations and guidelines and the consequences (e.g., overpayment demands, restitution, penalties, criminal, civil and administrative liability, exclusion from the Federal health care programs) both to the individual and Luzzi that may ensue from any violation of such requirements.

Luzzi agrees to arrange for each new employee to participate in such training no later than fifteen (15) days after the person begins to work for Luzzi. Until the person has received the requisite training, such new employee shall work under the direct supervision of an employee who has received the required training.

This training program shall provide for no less than four (4) hours of training annually for each person.

At a minimum, the training sessions shall cover the following topics:

- 1. Luzzi's obligations under this Agreement;
- 2. All applicable Federal health care program stanues, rules, regulations, and

guidelines related to reimbursement, and the legal sanctions for improper billing or other violations of these standards; and

The written policies and procedures developed pursuant to subsection C. above, including the proper billing standards and procedures for the submission of accurate claims to the Medicare, Medicaid and other Federal health care programs.

Luzzi and each employee and agent shall date and sign a certification indicating attendance at the training session and further attesting to an understanding of the provisions in the policies and procedures and all applicable Federal health care program standards addressed in training. These certifications will be maintained by Luzzi and shall be made available for inspection by OIG or its duly authorized representatives. At least one copy of the training materials or a detailed description of the topics covered during the training session shall be kept with the certifications.

## E. INDEPENDENT REVIEWS

On at least an annual basis and for the duration of this Agreement, Luzzi agrees to contract with an independent third-party reviewer (e.g., a health care billing auditor or a consultant) (hereinafter the "independent reviewer") to undertake a review of a statistically valid sample of the claims submitted by Luzzi and his agents and/or employees to the Federal health care programs. The purpose of this review is determine whether the claims are in compliance with the appropriate billing requirements. This review will be conducted by an independent and appropriately trained person or entity with knowledge of Federal health care program statutes, regulations, requirements, and reimbursement policies and procedures. These reviews shall cover, at a minimum, the preceding one (1) year period and shall seek to determine that the claims submitted to the Federal health care programs are medically necessary and covered services under applicable program guidelines and that the claims are appropriately coded and billed. At the conclusion of each review, the independent reviewer shall prepare a report describing the review's parameters, methodologies and procedures, as well as presenting the review findings and the reviewer's conclusions and recommendations. A copy of this report shall be included in Luzzi's Annual Reports to OIG.

If any of these reviews uncovers claims processing and/or billing policies, procedures or practices that result in material deficiencies, Luzzi shall notify the

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entity in charge of processing the claim for reimbursement (such as the Medicare carrier or other federal health care payor), within fifteen (15) days of discovering the deficiency and take remedial steps within thirty (30) days of discovering the deficiency (or such additional time as may be agreed to by the payor) to correct the problem, and prevent the deficiency from recurring.

Contemporaneous with Luzzi's notification to the payor as provided above, Luzzi shall notify OIG of: (1) all of the information provided to the payor in returning the overpayment; (2) the name and the address of the payor to which the overpayment was sent; (3) Luzzi's findings concerning the material deficiency; (4) Luzzi's actions to correct such material deficiency; and (5) any further steps Luzzi plans to take to address such material deficiency and prevent it and similar billing deficiencies from recurring.

For purposes of this Agreement, a "material deficiency" shall mean anything that involves: (i) a substantial overpayment relating to the Federal health care programs; (ii) conduct that impairs the financial integrity of the Federal health care programs and that clearly violate the Federal health care program statutes, regulations or written directives issued by the Health Care Financing Administration ("HCFA") and/or its agents; or (iii) serious quality of care implications for Federal health care program patients. A material deficiency may be the result of an isolated event or a series of occurrences.

If Luzzi learns of any overpayment (regardless of its size and regardless of whether it results from a material deficiency) received from a Federal health care program, Luzzi shall notify the appropriate payor, make appropriate refunds and take any steps necessary to prevent any recurrence.

## IV. SELF-DISCLOSURE OF PROBABLE VIOLATIONS

During the term of this Agreement, Luzzi agrees to report to OIG any reliable evidence of actions or omissions by Luzzi and/or his employees and agents (acting within the scope of employment or agency) that Luzzi believes may constitute a probable violation of any state or Federal criminal, civil or administrative statute, regulation, or rule governing a Federal health care program. Luzzi must make the required disclosure no later than forty-five (45) calendar days after becoming aware of the existence of the probable violation.

Any disclosures made pursuant to this paragraph shall contain a certification by

Luzzi that the matter at issue has been fully investigated and that appropriate corrective actions have been taken to ensure compliance with all state and Federal civil, criminal, and administrative statutes, regulations and rules governing all Federal health care programs. Nothing in this paragraph waives OIG's right to enforce any and all statutes and regulations governing any Federal health care program, subject to the release provisions of the Stipulation and Order of Settlement and Dismissal into which this Agreement is incorporated by reference.

#### OIG INSPECTION, AUDIT AND REVIEW RIGHTS V.

In addition to any other right OIG may have by statute, regulation, contract or pursuant to this Agreement, OIG or its duly authorized representative(s) may examine Luzzi's books, records, and other documents and supporting materials in his possession or under his control for the purpose of verifying and evaluating: (i) Luzzi's compliance with the terms of this Agreement; and (ii) Luzzi's compliance with the requirements of the Federal health care programs. OIG, HCFA, or the appropriate Federal health care program contractor may conduct unannounced on-site visits at any time to review patient medical records and other related documentation for the purpose of verifying and evaluating Luzzi's compliance with the statutory and regulatory requirements of the Federal health care programs.

#### VI. REPORTS

### IMPLEMENTATION REPORT

Within one hundred twenty (120) days of the effective date of this Agreement, Luzzi shall provide the OIG with a written report demonstrating that he has complied with the Program's requirements. This report, known as the "Implementation Report," shall include:

- A copy of the notice Luzzi posted in his office as described in Section III.B. 1.
- 2. A certification signed by Luzzi attesting that all employees have completed the initial training required by Section III.D. as well as a summary of what the training included. The training materials will be made available to OIG upon request.
- 3. A copy of the written policies and procedures required by section III.C. of this Agreement.

A certification from Luzzi stating that he has reviewed the Implementation 4. Report, he has made a reasonable inquiry regarding its content and believes that, upon his inquiry, the information is accurate and truthful.

#### В. ANNUAL REPORTS

Luzzi agrees to make annual written reports (each one of which is referred to throughout this Agreement as the "Annual Report") to OIG describing the measures he has taken to implement and maintain the Program and ensure compliance with the terms of this Agreement. In accordance with the provisions above, the Annual Report shall include:

- A description, schedule and topic outline of the training programs 1. implemented pursuant to section III.D. of this Agreement, and a written certification from all appropriate personnel that they received training pursuant to the requirements set forth in section III.D. of this Agreement.
- 2. A copy of the audits and reviews conducted pursuant to section III.E. of this Agreement relating to the year covered by the Annual Report; a complete description of the findings made during the reviews; copies of any disclosure notice documents made by Luzzi pursuant to this section; and any corrective actions taken.
- 3. A certification signed by Luzzi certifying that he has reviewed the Annual Report, he has made a reasonable inquiry regarding its content and believes that, upon his inquiry, the information is accurate and truthful.

The first Annual Report shall be submitted no later than one year and thirty (30) days after the effective date of this Agreement. Subsequent Annual Reports will be submitted on the anniversary date of the date of submission of the first Amnual Report

# NOTIFICATIONS AND SUBMISSION OF REPORTS

Unless otherwise modified in accordance with section IX below, all notifications and reports required under the terms of this Agreement shall be submitted to the entities listed below:

If to OIG:

Civil Recoveries Branch - Compliance Unit Office of Counsel to the Inspector General

Office of Inspector General

U.S. Department of Health and Human Services

330 Independence Avenue, SW Cohen Building, Room 5527 Washington, DC 20201 Tel. 202.619.2078

Tel. 202.619.2078 Fax 202.205.0604

If to Luzzi:

Angelo Luzzi, D.P.M. 2 Hidden Acres Drive Voorhees, NJ 08043 Tel. 609.772.6311

# VIII. BREACH AND DEFAULT PROVISIONS

Full and timely compliance by Luzzi shall be expected throughout the duration of this Agreement with respect to all of the obligations herein agreed to by Luzzi. In the event of Luzzi's failure to comply with any of the obligations in this Agreement, the Agreement may be deemed in breach and the parties shall proceed in the appropriate manner as described below.

## A. REMEDIES FOR MATERIAL BREACH OF THIS AGREEMENT

If Luzzi engages in conduct that OIG considers to be a material breach (as defined below) of this Agreement, OIG may determine to exclude Luzzi from participation in the Federal health care programs. Upon making its determination, OIG shall notify Luzzi of the alleged material breach by certified mail and of its intent to exclude as a result thereof (this notice shall be referred to hereinafter as the "Intent to Exclude Letter"). Luzzi shall have thirty-five (35) days from the date of the letter to:

- (1) cure the alleged material breach; or
- demonstrate to the OIG's satisfaction that the alleged material breach cannot be cured within the thirty-five (35) day period, but that Luzzi has begun to take action to cure the material breach and that Luzzi will pursue such action with due diligence. Luzzi shall, at this time, submit a timetable for curing the material breach for the OIG's approval.

If at the conclusion of the thirty-five (35) day period (or other specific period as subsequently agreed by OIG and Luzzi), Luzzi fails to act in accordance with provisions 1 or 2 above, OIG may initiate steps to exclude Luzzi from participation in the Federal health care programs. OIG will notify Luzzi in writing of its determination to exclude him (this letter shall be referred to hereinafter as the "Exclusion Letter").

## B. DISPUTE RESOLUTION

Upon OIG's delivery to Luzzi of its Exclusion Letter, and as an agreed upon contractual remedy for the resolution of disputes arising under the obligations in this Agreement, the OIG may initiate steps to exclude Luzzi from participation in the Federal health care programs. Luzzi shall be emitted to certain due process rights similar to those afforded under 42 U.S.C. § 1320a-7(f) and 42 C.F.R. § 1005. Specifically, the OIG's determination to seek exclusion shall be subject to review by a Department of Health and Human Services ("HHS") Administrative Law Judge ("ALJ") in a manner consistent with the provisions in 42 C.F.R. §§ 1005.2-1005.21. The ALJ's decision, in turn, may be appealed to the HHS Departmental Appeals Board ("DAB") in a manner consistent with the provisions in 42 C.F.R. § 1005.21. OIG and Luzzi agree that the decision by the DAB, if any, shall constitute the final decision for purposes of the exclusion under this Agreement.

For purposes of this section, a "material breach" shall mean: (i) a failure to report a material deficiency, take corrective action and pay the appropriate refunds, as provided in section III.E of this Agreement, (ii) repeated or flagrant violations of the obligations under this Agreement, including, but not limited to, the obligations addressed in section VI.A, VI.B and IX. of this Agreement, or (iii) a failure to retain and use an independent reviewer for the purposes described in section III.E.

## IX. New Entities or Locations

In the event that Luzzi purchases or establishes new business units after the effective date of this Agreement, Luzzi shall notify OIG of this fact within thirty (30) days of the date of purchase or establishment. This notification shall include the location of the new operation(s), phone number, fax number, Federal health care program provider number(s) (if any), and the corresponding payor(s) (contractor specific) that has issued each provider number. All employees at such locations shall be subject to the requirements in this Agreement that apply to new employees (e.g., completing certifications and undergoing training). Luzzi represents that to the extent legally

possible, he will severe all professional and financial relationships with Joseph Picciotti, D.P.M., and shall not enter into a new professional or financial relationship with Joseph Picciotti, D.P.M. during the term of this Agreement.

# X. EFFECTIVE AND BINDING AGREEMENT

Consistent with the provisions in the Stipulation and Order of Settlement and Dismissal pursuant to which this Agreement is reached, and into which this Agreement is incorporated, Luzzi and OIG agree as follows:

- this Agreement shall be binding on the successors, assigns and transferees of Luzzi who employ, contract with, or otherwise retain Luzzi for the purpose of rendering services for which reimbursement is sought from the Federal health care programs;
- 2. this Agreement shall become final and binding only upon signing by each respective party hereto; and
- 3. any modifications to this Agreement shall be made with the prior written consent of the parties to this Agreement.

IN WITNESS WHEREOF, the parties hereto affix their signatures:

For: Ancelo Luzzi, D.PM.

Angelo Luzzi, D.P.M.

Counsel for Angelo Luzzi, D.P.M.

Date

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For: Office of Inspector General of the Department of Health and Human Services

Lewis Morris, Esquire

Assistant Inspector General for Legal Affairs Office of Counsel to the Inspector General

Office of Inspector General

U. S. Department of Health and Human Services